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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,280	08/21/2001	Jonathan D. Chesnut	INVIT1300-1	8805

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EXAMINER

HASHEMI, SHAR S

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/935,280

Applicant(s)

CHESNUT ET AL.

Examiner

Shar Hashemi

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5,1213.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: "Notice to Comply".

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Preliminary Amendment (filed 26 November 2001) was received and entered as Paper No. 6. The claims pending in this application are **Claims 1-64**.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on 10/01/01, 11/30/01, 09/30/02, and 11/04/02 was entered as paper Nos. 4, 5, 12, and 13. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Priority

3. Applicant's claim for domestic priority under 35 U.S.C. 119(e) to provisional application 60/226,563 is acknowledged.

Drawings

4. The drawings are objected to because Figures 4, 5, 7, 10, and 12-14 contain nucleotide sequences that lack required SEQ ID NO "identifiers." A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Sequence Rules

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5. This application does NOT comply with the sequence rules (see "Notice to Comply").

This application contains sequence disclosures (see Figures 4, 5, 7, 10, and 12-14) that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Sequence disclosures **must** have SEQ ID NO identifiers. The initial computer readable form (CRF) copy of the "Sequence Listing" could not be read by the Scientific and Technical Information Center. Furthermore, applicant must provide: 1) a **new** computer readable form (CRF) copy of the "Sequence Listing," 2) a paper copy of the "Sequence Listing," 3) an amendment directing its entry into the specification, and 4) a statement that the content of the paper and the computer readable copies are the same and where applicable, include no new matter (see "Notice to Comply...").

APPLICANT IS GIVEN THE RESPONSE PERIOD SET FORTH IN THIS OFFICE ACTION IN WHICH COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821 – 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period. Applicant is requested to return a copy of the attached Notice to Comply with the response. The application is not in compliance for the reason(s) set forth on the attached Notice to Comply With the Sequence Rules or CRF Diskette Problem Report.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The SEQ ID NO: 16 renders claim 52 indefinite. It is unclear as to whether the “ds nucleic acid molecule” or the “pUni/V5-His version A vector” is encoded by SEQ ID NO: 16. Furthermore, no search of SEQ ID NO: 16 can be performed because the CRF is defective. Amending the claim to clarify the nexus to SEQ ID NO: 16 and submitting a new CRF would obviate the rejection.

B) Claim 54 contains the trademark/trade name pCR. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a vector and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-51 and 53-64 are rejected under 35 U.S.C. 102(e) as being anticipated by

Heyman et al (US 2001/0044137 A1 November 22, 2001).

Heyman et al teach a kit, composition, and a method for generating a directionally linked recombinant nucleic acid molecule comprising the limitations set forth in claims 1-51 and 53-64 (see whole document, especially page 2, par. 13-18; page 3, par. 19-21; page 4, par. 28-35; page 5, par. 43-51, page 6, par. 55-60; page 7, par. 66-84; page 12, par. 173-178).

10. Claims 1-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Hodgson (US 2002/0025561 A1 February 28, 2002).

Hodgson teach a method for generating a directionally linked recombinant nucleic acid molecule comprising the limitations set forth in claims 1-20 (see whole document, especially page 2, par. 14-23; page 4, par. 38-41; page 5, par. 42-46; page 6, par. 47-48).

11. Claims 1-51 and 53-61 are rejected under 35 U.S.C. 102(e) as being anticipated by Shuman (US 6,548,277 B1 April 15, 2003).

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Shuman teaches a composition and method for generating a directionally linked recombinant nucleic acid molecule comprising the limitations set forth in claims 1-51 and 53-61 (see whole document, especially col. 1, lines 58-67; col. 5, lines 10-59; col. 6, lines 13-60; col. 7, lines 15-67; col. 8, lines 20-67; col. 10, lines 5-50; col. 11, lines 19-49; col. 12, lines 40-67; col. 13, lines 15-48).


CONCLUSION

12. Claims **1-64** are rejected to for the reasons set forth above.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shar Hashemi whose telephone number is (703) 305-4840. The examiner can normally be reached Monday-Friday from 8:00AM – 5:00PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

The fax number for this examiner is (703) 746-9038. Before faxing any papers, please inform the examiner to avoid lost papers. Please note the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist, Tracey Johnson, whose telephone number is (703) 305-2982.

Examiner Hashemi



ETHAN WHISENANT
PRIMARY EXAMINER